UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,529	07/24/2000	PATRICIA KANNOUCHE	192863US0PCT	6934

22850 7590 10/09/2002

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202

EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	PAPER NUMBER
1634	12

DATE MAILED: 10/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/555,529	KANNOUCHE ET AL.	
Examiner	**Art Unit**	
Diane Johannsen	1634	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *6-23 and 26-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,24,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

1. This application is a 371 of PCT/FR98/02667, filed December 9, 1998. The International Search Report and International Preliminary Examination Report for PCT/FR98/02667 have been received. It is noted that the references cited in the Search Report and Preliminary Examination Report will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

Election/Restrictions

2. Applicants' election with traverse of Group I, claims 1-5, 24-25, and 29 in Paper No. 12 is acknowledged. The traversal is on the following ground(s). Applicants argue that the Kannouche et al reference was not available to subscribers until after the foreign priority date of the instant application (December 9, 1997). Applicants have provided documentation from Elsevier indicating that the reference became available to subscribers in January of 1998.

Applicants argument has been thoroughly considered but is not found persuasive. Applicants' foreign priority document is in a foreign language (French), and a certified translation of that document has yet to be filed. While the response indicates that "any further documentation necessary to support this position shall be provided as needed," the certified translation - which is needed to determine what elements of the claimed invention find support in the foreign priority document – is not before the

examiner. Thus, at the present time, applicant is entitled to a priority date of December 9, 1998, and the Kannouche et al reference constitutes prior art with respect to the claimed invention. It is also noted that a brief review of the foreign document indicates that there are significant differences between the foreign document and the instant application (e.g., the number of Figures and sequences disclosed differ, the content of the Sequence Listings differ, etc.).

Applicants further state in their traversal that "the claims of Group V depend directly from the claims of Group III, and as such these claims can not be separated." This argument with respect to Groups III and V is also not found persuasive. When considering unity of invention, a dependent claim is considered to be one that "contains all features of another claim and is in the same category of claim as that other claim (the expression 'category of claim' referring to the classification of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.)" (*MPEP* 1850 A). The claims of Group III, which are drawn to products, are of a different category than the claims of Group V, drawn to methods. It is noted that dependent claims 14 and 15, drawn to protein products "according to claim 13," were properly included with independent product claim 13. Further, it is noted that while PCT Rule 13 allows the inclusion in a single application of certain combinations of different categories of claims (e.g., claims to a product and a method of using that product) when a special technical feature is present, the proteins of Group III are not the first product recited in applicants' claims, and thus are not part of the main invention in the claims, such that the claimed proteins might be combined with other categories of

claims in a single Group. See 37 *CFR* 1.475 and *MPEP* 1850 C; in particular, 37 *CFR* 1.475 (d), which states "If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims."

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 6-23 and 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Specification

4. The disclosure is objected to because of the following informalities:

The specification does not include a separate Brief Description of the Drawings, as discussed in MPEP 608.01(f). This objection could be overcome by, e.g., amending the specification to insert the heading "Brief Description of the Figures" at the appropriate location on page 10.

Appropriate correction is required.

5. The title of the invention is not descriptive of the elected invention. In particular, it is noted that none of the elected claims are drawn to methods/applications. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

6. The use of the trademarks TSA™ and Vectashield® have been noted in this application. The trademarks should be capitalized wherever they appear and be accompanied by the applicable generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5, 24-25 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 29 are indefinite over the recitation of the term "nucleic acid sequence" and "sequence" in the first line of claims 1-5 and in the fourth line of claim 29. It is unclear as to whether applicants' intent is to actually claim information, as suggested by the recitation of a "sequence" (as opposed to, e.g., a polynucleotide or nucleic acid molecule) or whether applicants' intent is to claim, e.g., isolated nucleic acids having a particular sequence. Clarification is required.

Claims 1 and 3-4 are indefinite over the recitation of the language a "sequence" that "presents" a sequence. It is unclear as to whether the language "presents" is intended to refer to a sequence (or nucleic acid) consisting of a sequence, comprising a sequence, etc. Accordingly, the metes and bounds of the claim cannot be ascertained.

Claim 1 is indefinite over the recitation "is capable of expressing a functional human kin17 protein." It is unclear as to how this recitation is intended to limit the claim. For example, is this language intended to indicate that a complete kin17 open reading frame must be present, that sequences necessary for expression must be present, that the "sequence" must otherwise be capable of performing protein expression, etc. Clarification is required.

Claims 3-4 are indefinite over the recitation of the term "corresponds." It is unclear as to what type of relationship between proteins would be encompassed by this terminology. Neither the specification nor the art provides a clear definition for this language as it relates to a relationship between proteins. Clarification is required.

Claim 5 is indefinite over the recitation of the limitations "the gene encoding the human kin17 protein" and "the RNA of the Kin17 gene." There is insufficient antecedent basis for these limitations in the claim.

Claim 5 is indefinite over the recitation of the language "Fragments of the sequence.....they are selected from...." It is unclear as to whether this language is intended to require, e.g., a composition comprising multiple copies of the same fragment of SEQ ID NO: 1, whether this language is intended to require a composition comprising more than one of SEQ ID NOS 4-21 and 33, etc. Clarification is required.

Claims 24-25 are indefinite because it is unclear from the language of claim 24 as to what is to be "selected from the group consisting of the sequences SEQ ID NO. 1, 2, 3, 33, and 34:" the vector, the "sequence encoding" a protein, the protein, or the "fragment of it." Clarification is required.

Claim 29 is indefinite because it is unclear as to what type of product (or products) is (are) intended to be encompassed by the claim. For example, is applicants' intent to claim a kit comprising multiple reagents in separate containers, a composition comprising multiple nucleic acid molecules having different sequences, etc. Clarification of the structural properties of the product of claim 29 is required.

Claim 29 is indefinite over the recitation of the limitation "these sequences." There is insufficient antecedent basis for this limitation in the claim.

Claim 29 is indefinite over the recitation of the term "they" in line 4 of the claim. It is unclear as to whether the term "they" refers back to the "Reagents" or to the "sequences" of line 3.

Claim 29 is indefinite over the recitation of the phrase "the fragments A of 453-bp, B of 1265-bp and C of 224-bp." It is unclear as to what fragments are intended to be encompassed by this language, as the claim does not refer to, e.g., fragments of a particular nucleic acid, portions of a particular SEQ ID NO, etc. Clarification is required with respect to what molecules are intended to be encompassed by the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 2-3 and 24 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Kannouche et al (Biochimie 79:599-606 [issue dated 10/1997; available

1/1998]). It is noted that the inventive entity of the instant invention is distinct from the authorship of the Kannouche et al reference and that this rejection may be overcome by the filing of a Katz-type declaration or by establishing priority of the invention to 12/9/1997 by filing a certified translation of French priority document 97-15536.

Kannouche et al disclose the plasmid pCMVKin17ΔHR, which is an expression vector comprising the mouse *kin17* gene having a deletion of the sequences encoding amino acids 129-228 of the mouse Kin17 protein (see entire reference, especially Table I and text of p. 600). Accordingly, Kannouche et al clearly anticipate claims 2-3 and 24. Regarding claim 3, It is noted that it is an inherent property of the plasmid taught by Kannouche et al that it includes the sequence of instant SEQ ID NO: 2.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kannouche et al (Biochimie 79:599-606 [issue dated 10/1997; available 1/1998]) in view of Wu et al (Gene 190:157-162 [4/1997]). It is noted that the inventive entity of the instant invention is distinct from the authorship of the Kannouche et al reference and that this rejection may be overcome by the filing of a Katz-type declaration or by establishing priority of the invention to 12/9/1997 by filing a certified translation of French priority document 97-15536.

Kannouche et al disclose the plasmid pCMVKin17ΔHR, which is an expression vector comprising the mouse *kin17* gene having a deletion of the sequences encoding amino acids 129-228 of the mouse Kin17 protein (see entire reference, especially Table I and text of p. 600). It is noted that it is a property of the plasmid taught by Kannouche et al that it includes the sequences of instant SEQ ID NOs: 2 and 34. Kannouche et al employ their plasmid to determine the intracellular location of the kin17ΔHR truncated protein in HeLa cells; the location of kin17ΔHR was determined by staining with antibodies (see p. 602). Kannouche et al do not disclose an expression vector in which the kin17 sequences of the construct are fused "with a gene which encodes a fluorescent protein," as set forth in claim 25. Wu et al disclose that expression vectors comprising genes of interest fused to a gene encoding green fluorescent protein allow the production of a fusion protein that may be detected visually without the use of "cofactors or substrates" (see entire reference, especially p. 157). Wu et al disclose that

such fusion proteins "localize in the correct subcellular compartments in the mammalian system" (p. 162). In view of the teachings of Wu et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the expression vector of Kannouche et al so as to have prepared an expression vector comprising the gene encoding kin17ΔHR fused to the gene encoding green fluorescent protein. An ordinary artisan would have motivated to have made such a modification in order to have accurately determined the intracellular location of kin17ΔHR in various types of cells without the need for the additional reagents and steps necessitated by detection with cofactors or substrates such as antibodies, for the advantages of convenience, efficiency and cost-effectiveness.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
September 24, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600